

REMARKS

The Office Action mailed February 3, 2010, has been carefully considered and the following is responsive thereto. The amendment to claim 1 (relating to the Brookfield LVF viscometer) is supported by the present application at page 7, lines 4-6 from the bottom. Claim 2 is incorporated into claim 1. New claims 46-48 are supported by the present specification at page 9, lines 1-9 from the bottom. Applicants respectfully request reconsideration of the outstanding rejection and entry of the foregoing amendments and new claims.

As background, an Appeal Brief was filed in the present application on September 30, 2009. The sole rejection on appeal was a rejection of claims 1-28 under 35 USC § 103 as being unpatentable over Jonsson in view of Guiseley. This rejection has been withdrawn. However, the Examiner has issued a new rejection using the same references as those in the prior rejection, but adds a new reference (Resch) to support the outstanding rejection.

At pages 3-5 of the Office Action, the Examiner rejected claims 1-28 under 35 USC § 103 as being unpatentable over Jonsson in view of Guiseley and Resch.

The Examiner's position is essentially that Jonsson discloses a food composition in the form of a gel comprising soluble solids in the range of about 50% to about 90 % by weight and a carrageenan component present in an amount sufficient to gel. The Examiner indicates that the gel of the present invention (claiming a carrageenan having a viscosity of 5 to less than 10 cP) is not disclosed in Jonsson. However, the Examiner asserts that Guiseley discloses the use of carrageenans having the presently claimed viscosity in milk products. Furthermore, the

Examiner newly cites Resch for purportedly disclosing the carrageenan of the present invention, the gelling times in claims 3-5 and the carrageenan salts of claims 9-14. Therefore, the Examiner argues that it would have been obvious to incorporate the presently claimed carrageenans in the gelled food products of Jonsson since, in the Examiner's view, Guiseley and Resch teach "that carrageenan having such viscosity are effective in stabilizing food products" (see the Office Action at page 5; emphasis added).

Applicants respectfully traverse the foregoing rejection based upon the reasons of record, as well as additional reasons set forth herein. As is discussed in more detail below, Guiseley expressly teaches away from using the specific carrageenans disclosed therein in gel applications and, contrary to the Examiner's reading of Resch, Resch fails to disclose or suggest the carrageenans of the present invention or their use in gel and gel film applications. Furthermore, nothing in the prior art, alone or in any combination, suggests that the carrageenans of the present invention would lower the gelling temperature of a gel when compared to carrageenans of similar type and content at higher molecular weights.

1. The Present Invention

Claims 1-25 are directed to a homogeneous, thermoreversible **gel** comprising carrageenan wherein the carrageenan has a viscosity of 5 to less than 10 cP at 75 °C when measured using a Brookfield LVF viscometer, spindle #1, at 60 r.p.m., in a 0.10 molar aqueous sodium chloride solution containing 1.5% by weight of the carrageenan based on the weight of all components in

the solution, and optionally at least one of a plasticizer, a second film former, a bulking agent, and a pH controlling agent, wherein the gel has a solids content of at least 40% and the carrageenan is present in an amount of at least 70% of all carrageenan present in the gel.

Claim 27 is directed to the gel of claims 1-26 being a **gel film**.

In high solids systems, for example, greater than 40% solids, carrageenan gel forming compositions have been known to create highly viscous systems that create processing problems when the gel is made, e.g., such processing requires significant heat, shear, handling in order to prevent premature gelling or formation of gels and gel films that are less than fully homogeneous (resulting in gels of weaker strength) (e.g., see the present specification at page 3, lines 6-10). Important industrial applications, such as the manufacture of soft capsules, hard capsules, edible products (gummies, candies, etc.), solid forms encapsulating powders, tablets, etc., could benefit from the use of particular carrageenan gels that gel at reduced temperatures (e.g., see the present specification at page 3, lines 10-13).

It has long been believed that the gelling temperature of carrageenan is independent of its molecular weight (e.g., see the present specification at page 3, lines 13-15).

As explained below, at 75 °C, carrageenan is soluble in water and aqueous sodium chloride solutions and, as a result, the viscosity of any such solution at 75 °C is a reasonable indicator of the molecular weight of the carrageenan itself. As noted throughout the present application, carrageenans having the claimed viscosity at 75 °C have a **reduced molecular weight** (e.g., see the title and page 7 of the present application explaining that such carrageenans have reduced molecular weights).

To Applicants' surprise, in high solids carrageenan gels, such as at least 40% solids, the gels and gel films containing such reduced molecular weight carrageenans as referenced herein result in the formation of gels and gel films having a highly desirable and unexpected lowering of the gelling temperature (e.g., see the present specification at page 3, lines 15-18) when compared to carrageenans of similar type and content at higher molecular weight.

2. Jonsson Fails to Disclose or Suggest the Presently Claimed Carrageenan

Jonsson is directed to the stated problem of overcoming the limited solubility of using carrageenan in high solids systems for food compositions. More specifically, the Jonsson invention is directed to food compositions comprising soluble solids in the range of 50% to 70% by weight, at least 70% by weight thereof being a sweetening system comprising sucrose and non-sucrose sweeteners. Jonsson discloses that the use of such a sweetening system surprisingly allows the carrageenan component to be dissolved in a high solids system.

Importantly, Jonsson discloses that "...any carrageenan component, which will provide the required gelling capability, may be employed in a food composition according to the present invention" (emphasis added; see col. 6, lines 42-44).

The Examiner admits that Jonsson does not disclose the gel of the present invention having a carrageenan possessing the claimed viscosity. As a result, the Examiner relies on Guiseley and Resch for this teaching. However, as noted below, neither Guiseley nor Resch teach or suggest the use of the presently claimed carrageenans in gel and gel film applications.

3. Guiseley *Expressly Teaches Away* from the Use of the Presently Claimed Carrageenan in a Gel and Gel Film and Actually *Supports* the Patentability of the Present Claims

The Examiner relies on Guiseley as suggesting the use of the presently claimed carrageenan in the teachings of Jonsson. As noted above, Jonsson teaches that the carrageenans useful therein are those that “will provide the required gelling capability” (see col. 6, lines 42-44).

However, Applicants explain that Guiseley discloses and suggests the low molecular weight carrageenan extract of the Guiseley invention to be used as a stabilizer for chocolate milk because such carrageenan will *not* lead to gelation. Guiseley states:

One such performance advantage...of the modified *Euchema Cottonii* extractive of this invention is its ability to provide stabilization of chocolate milk at relatively high use levels without excessive thickening of the product...This characteristic of the modified extractive of this invention is of particular importance in those circumstances where the chocolate milk is subjected to extreme shear stresses during processing, and the dairyman wishes to provide stabilization *without running the risk of gelation*, as is encountered when using a more conventional stabilizer at a high enough level to accommodate for the effects of shear stresses” (see col. 5, lines 29-42; emphasis added).

Therefore, the carrageenan materials of the Guiseley invention are specifically disclosed as being useful therein because they would NOT lead to gelation. As a result, one skilled in the field would NOT have been motivated to use the carrageenans from Guiseley (disclosed to be useful because they would not lead to gelation) in the teachings of Jonsson (which discloses the need to use carrageenans known to have sufficient gelation in high solids food compositions) or Resch.

At page 3 of the final rejection dated February 4, 2009, the Examiner notes Applicants' argument above, but does not appear to completely address it or the full teachings of Guiseley. Applicants fully understand that the Examiner is citing Guiseley "to show that the viscosity values of the carrageenan recited in the instant claims are known in the art" (see page 3, paragraph 5, thereof). However, this argument is confusing and legally irrelevant as the present invention is directed to **gels** and **gel film** applications and Guiseley clearly teaches **not** to use the carrageenan materials disclosed therein in gel and gel film applications.

The Examiner further notes in the Advisory Action dated July 22, 2009, that the instant claims include up to 30% of carrageenans that do not fall within the instantly claimed viscosity of 5 to less than 10 cP. The Examiner's point here is also not understood and is believed to confuse what is required to establish a proper *prima facie* case of obviousness.

That is, the present gels and gel films comprise up to 70% of the carrageenan having the claimed viscosity range. None of the cited prior art, alone or in any combination, suggests the use of the presently claimed carrageenan in a gel or gel film. (In fact, Guiseley, expresses teaches away from using the presently claimed carrageenan in a gel as discussed above.) The

Examiner's reference in the Advisory Action to other possible carrageenans that may be included does not somehow cure this deficiency and is clear legal error.

The Examiner did not offer a single comment in the outstanding Office Action regarding the clear teaching away of Guiseley. As set forth in the MPEP at 2143.03 VI:

“A prior art reference must be considered in its entirety; i.e., as a whole, including portions that would lead away from the claimed invention.” (Emphasis not added.)

The Examiner is respectfully requested to consider the teachings of Guiseley as a whole including the clear and express teachings in Guiseley NOT to use the carrageenans of the present invention in gel and gel film applications.¹

It is respectfully submitted that a proper *prima facie* case of obviousness has not been established over any combination of Jonsson, Guiseley and Resch in view of Guiseley's express teaching away of the carrageenan taught therein in milk products. In fact, Guiseley actually supports the unexpected nature of the present invention by clearly teaching NOT to use the carrageenans therein in gel and gel film applications. Withdrawal of the rejection is requested on this basis.

4. Resch Does Not Cure the Deficiencies of Jonsson and Guiseley

¹ See MPEP 707(f) requiring the Examiner to respond to all Applicants' traversals.

As noted above, the Examiner admits that Jonsson does not disclose a gel comprising the presently claimed carrageenans and Guiseley clearly teaches away from the use of the presently claimed carrageenans in gel and gel film applications.

Prosecution of this application was reopened by the outstanding Office Action and Resch was added to the rejection on the basis that Resch purportedly discloses gels comprising the presently claimed carrageenans of claim 1, gelling temperatures of claims 3-5 and ionic components of claims 9-14.

Applicants respectfully traverse this reading of Resch and explain that, contrary to the Examiner's position, Resch does not disclose or suggest a carrageenan having a viscosity of 5 to less than 10 cP when measured at 75 °C and, further, does not in any way suggest the use of such carrageenan in gel and gel film applications.

The carrageenan used in the gels of the present invention has a viscosity of 5 to less than 10 cP when measured at 75 °C in a 0.10 molar aqueous sodium chloride solution. Applicants explain that it is well known that the molecular weight of carrageenan can be assessed by measuring the viscosity of the carrageenan when such is soluble in a given solvent (in this case, a 0.10 molar aqueous sodium chloride solution).² At 75 °C, Applicants further explain that the carrageenan of the present invention is soluble in the aqueous sodium chloride solution.³ As a result, the viscosity of the solution at 75 °C is a reasonable indicator of the molecular weight of

² See page VII/2, Polymer Handbook, submitted herewith explaining that the material must be soluble in the solvent to determine its molecular weight.

³ See page 352, Food Colloids, submitted herewith explaining that "all carrageenans ...are soluble in hot water."

the carrageenan itself and, further, that, under such tested conditions, the viscosity of 5 to less 10 cP is evidence of carrageenans having a reduced molecular weight.

In distinction, Resch discloses a dry powder of a gel film⁴ having a viscosity of between about 10 and 40 mPa-s when reconstituted in a 2% w/w solution at 25 °C. This test offers nothing about the molecular weight of the carrageenan itself.

First, the viscosity in Resch was measured at 25 °C, not 75 °C as the carrageenan of the present invention is measured.

Second, the dry powder in Resch that is indicated to have a viscosity of 10 to 40 mPa-s is a powder of a dry gel film and NOT a powder of the carrageenan itself. Applicants explain that the powder of the gel film in Resch swells in the water at 25 °C (generating the increase in viscosity that is shown in Resch), but would not be soluble in a 2% water solution at 25 °C.⁵ Since the powder of the dry gel film in Resch is not soluble in the 2% water solution at 25 °C, the viscosity given in Resch may be an indicator of the rheological properties of the solution, but cannot be an indicator of the molecular weight of the carrageenan itself.

Since one skilled in the art would readily know that the powder of the dried gel film of Resch is not soluble in the water solution at 25 °C and the viscosity provided therein is merely an indication of the rheological properties of the solution, it is respectfully submitted that one

⁴ The dry hydrocolloid powder is taught throughout Resch to be the product of heating the hydrocolloid/carrageenan solution above its gelation temperature (e.g., 50-95 °C) followed by cooling the solution to below the gelation temperature and drying to form the powder (e.g., see the Abstract, paragraphs 9, 19-23, and claim 1). This, therefore, is a powder of a dry gel film of the hydrocolloid. The powder of a dry gel film of Resch should not be confused with the powder of the carrageenan itself. In fact, it is the dry gelled powder of Resch that Resch indicates provides the unexpected rheological benefits over the carrageenan itself.

⁵ See US 6730,340, attached, disclosing that “Films composed primarily of carrageenan additionally exhibit excellent strength, are not soluble in cold water...” (see column 1, lines 34-36).

skilled in the art would not find any disclosure or suggestion in Resch about the molecular weight of the carrageenan used therein, much less a suggestion to use the low molecular weight carrageenan of the present invention.

As a result, nothing in Resch, alone or in combination with Jonsson or Guiseley, would teach or suggest the use of a carrageenan as in the present invention in gel or gel film applications.

In addition, while Resch may disclose broad gelling temperatures of carrageenan as a whole, nothing in Resch discloses or suggests that the gels of the present invention would have the specific gelling temperatures set forth in claims 3-5 when the carrageenan is iota carrageenan (claim 3), kappa carrageenan (claim 4) and kappa-2 carrageenan (claim 5) or the specific gelling temperatures as set forth in new claims 46, 47, and 48 with respect to each particular carrageenan. As further discussed below, Applicants explain that a surprising aspect of the gels made using the carrageenans of the invention is that such carrageenans “have been found to lower the gelling temperature of the resulting gel as compared to carrageenans of similar type and content having a higher molecular weight” (see the present application at page 8). This is a highly desirable property for gel applications. Nothing in the prior art cited by the Examiner suggests that gels made from the carrageenans of the present invention would have lower gelling temperatures when compared to carrageenans of similar type and content having a higher molecular weight. As a result, claims 3-5 are patentable over Resch, alone or in any combination, with Jonsson and Guiseley.

Finally, the Examiner's position that Resch discloses claims 9-14 is also not understood. The ionic components disclosed in Resch are salts (such as sodium chloride or potassium chloride) that are added to the solution to impact gelation or increase viscosity of the solution at 25 °C (see paragraphs 18 and 26), but the disclosure of such salts in Resch does not relate to the cations of the carrageenan itself in claims 9-14. Moreover, this disclosure in Resch says nothing about the specific carrageenan cation contents of claims 10-14. As a result, there is no suggestion in any combination of cited art to use the specific carrageenans of the present invention having the cation and cation content of claims 9-14 in gel and gel film applications.

5. The Presently Claimed Gel Films of Claim 27

Claim 27 is directed to the gels of the present invention being a gel film. The Examiner refers to Jonsson as purportedly disclosing film formers and relies on this disclosure in combination with Guiseley and Resch to somehow suggest the use of reduced molecular weight carrageenan in gel film applications. However, nothing in Jonsson (no disclosure or suggestion of the presently claimed carrageenans), Guiseley (directed to milk products) or Resch (no disclosure or suggestion of the presently claimed carrageenans) would teach or suggest the use of the specific carrageenans in the present invention in gel film applications.

6. Nothing in the Prior Art, Alone or in any Combination, Teaches the Lowering of the Gelling Temperature associated with the Carrageenans of the Present Invention

As noted above, the specific carrageenans of the present invention have been found to lower the gelling temperature of the resulting gel as compared to carrageenans of similar type and content having a higher molecular weight. Nothing in the prior art, alone or in any combination, suggests the lowering of the gelling temperature when compared to similar carrageenans having a higher molecular weight.

For example, as noted at page 8 of the present application, Applicants have found that the iota carrageenans of the present invention have reduced the gelling temperature from about 81 °C (iota carrageenan having 3.37 % potassium and 1.3% calcium by weight of the carrageenan and a viscosity of 23 cP when measured under similar conditions) to about 34 °C (iota carrageenan of the invention having 3.37 % potassium and 1.3 % calcium by weight of the carrageenan and a viscosity of 6 cP) and from about 60 °C (iota carrageenan having 7.8% sodium by weight of the carrageenan (0% potassium and calcium) and a viscosity of 23 cP when measured under similar conditions) to about 30 °C (iota carrageenan of the invention having 7.5% sodium and 0.5% potassium by weight of the carrageenan and a viscosity of 6 cP).

Applicants have further found that the kappa carrageenans of the invention have reduced the gelling temperature from about 28 °C (kappa carrageenan having 5.4% sodium, 0.09% calcium, 0% potassium by weight of the carrageenan and a viscosity of 129 cP when measured

under similar conditions) to about 21 °C (kappa carrageenan of the invention having predominantly sodium cation and a viscosity of 8 cP). See page 9 of the application.

Furthermore, Applicants have found that the kappa-2 carrageenans of the invention have reduced the gelling temperature from about 35 °C (kappa-2 carrageenan having 7.4% sodium, 0.15% calcium, 0.67% potassium by weight of the carrageenan and a viscosity of 41 cP when measured under similar conditions) to about 25 °C (kappa-2 carrageenan of the invention having 7.7% sodium, 0.01% calcium, 1.0% potassium by weight of the carrageenan and a viscosity of 9 cP). See pages 9 and 10 of the present application.

As noted above, while Resch discloses a broad range of gelling temperatures for carrageenan as a whole, nothing in Resch, alone or in any combination with Jonsson or Guiseley, discloses or suggests that one could lower the gelling temperature of carrageenan gels by using the specific carrageenans of the present invention when compared to gels having carrageenans of similar type and content at a higher molecular weight.

7. Conclusion

In view of the foregoing, it is respectfully submitted that the Examiner has not established a proper *prima facie* case of obviousness. The Examiner admits that Jonsson does not disclose or suggest the presently claimed carrageenans in gel and gel film applications. Guiseley expressly teaches away from using the carrageenans therein in gel and gel film applications and actually supports the patentability of the present invention. Finally, Resch fails

to disclose or suggest the carrageenans of the present invention or their use in gel or gel film applications. Furthermore, nothing in the prior art, alone or in any combination, suggests that the carrageenans of the present invention would lower the gelling temperature of a gel when compared to carrageenans of similar type and content at higher molecular weights. As a result, it is respectfully submitted that claims 1-28 are unobvious and patentable over the combination of Jonsson, Guiseley and Resch. Accordingly, withdrawal of this section 103 rejection is respectfully requested.

In view of the above, the present application is believed to be in a condition ready for allowance. Reconsideration of the application is requested and an early Notice of Allowance is earnestly solicited.

Dated: April 16, 2010

Respectfully submitted,

By: /Paul A. Fair, Reg. No. 35,866/
Paul A. Fair, Esq.
Registration No.: 35,866
215-299-6723

Please forward all correspondence to:

Patent Administrator
FMC Corporation
1735 Market St.
Philadelphia, PA 19103

Attachments:

- 1) US 6,730,340
- 2) J.; Immergut, Edmund H.; Grulke, Eric A.; Abe, Akihiro; Bloch, Daniel R; Polymer Handbook (4th Edition); Section VII; 32 pages.
- 3) Food Colloids, Edited by Horace D. Graham, Chapter 8, Sulfated Seaweed Polysaccharides, Arthur L. Moirano, page 352, AVI Publishing Company, Westport, Connecticut, 1977.